UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,082	09/25/2000	Richard L. Scopp	6734.US.01	3368

23492 7590 01/16/2003

STEVEN F. WEINSTOCK
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

EXAMINER
DO, PENSEE T

ART UNIT	PAPER NUMBER
1641	9

DATE MAILED: 01/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/669,082	SCOPP ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4& 5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I, claims 1-17, 26 in Paper No. 7 is acknowledged.

Information Disclosure Statement

The information disclosure statements filed on February 26, 2001 and July 08, 2002 have been acknowledged and entered.

Claims Status

Claims 1-17, 26 are pending. Claims 18-25 are canceled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 26 are missing a critical step because the preamble recites "A method for decreasing interferences which result in inaccurate readings in serum or plasma sample" but the body of the claim fails to recite any step of decreasing the interferences in serum or plasma sample.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Petry et al. (US 6,406,858).

Petry teaches an improvement to the method of determining the concentration of an analyte in body fluid using at least two immunoreactants which specifically bind with separate epitopes of the analyte. The method comprises a step of adding a scavenger conjugate of an enzyme and a water-soluble protein or a non-proteinaceous natural, synthetic or semi-synthetic polymer or oligomer to reduce the interaction of the unknown interferents which result in inaccurate readings. The non-proteinaceous polymer is polylysine with molecular weights in the range of from 3 to 250 K Daltons. The specific binding assay is performed using magnetic particles as solid support. The analytes are Thyroid stimulating hormone, prostate specific antigen, troponin and insulin. (see col. 1, lines 5-10; col. 5, 2, lines 34-65; col. 3, lines 14-36; col. 4, lines 10-18; example 8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petry et al. (US 6,406,858).

Petry has been discussed above.

However, Petry fails to teach detecting free prostate specific antigen.

It would have been obvious to one of ordinary skills in the art to detect free prostate specific antigen since Petry's method can be used to detect prostate specific antigen. Such teaching is broad enough to encompass detection of free prostate specific antigen to one of ordinary skills in the art.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Petry (US 6,406,858) further in view of Massey et al. (US 5,798,083).

Petry has been discussed above.

However, Petry fails to teach acridinium as chemiluminescent label.

Massey teaches a chemiluminescent TSH immunoassay comprising a monoclonal anti-TSH antibody coated magnetic microparticles; an acridinium ester labeled polyclonal anti-TSH antibody. (See example 11).

It would have been obvious to one of ordinary skills in the art to use acridinium ester as labels as taught in Massey in the method of reducing interferences taught by Petry to detect TSH because acridinium ester is known for its sensitivity with low amount of analytes of interest in a sample. Since the interferences in the sample are also eliminated, acridinium labels would be more sensitive to very low amount of analytes present in the sample. Detection of such low amount of analytes of interest is helpful in the identification of diseases at early stage.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cantor (US 5,994,085) further in view of Diamandis (US 5,688,658).

Cantor teaches a method for detecting free prostate specific antigen (fPSA) comprising pretreating the sample to remove complex PSA and then assaying the fPSA by a sandwich immunoassay using two antibodies. The first antibody is specific for fPSA and is affixed on a solid phase. The second antibody is specific for another epitope site on the fPSA and contains a signal component that can be measured such as a fluorescer, luminescent molecule etc.

However, Cantor fails to teach using acridinium as luminescent label.

Diamandis teaches using chemiluminescent labels such as acridinium esters in immunoassay to detect prostate specific antigen (PSA). (see col. 5, lines 17-24).

It would have been obvious to one of ordinary skills in the art to use acridinium esters as chemiluminescent label as taught by Diamandis in the immunoassay method of Allard to detect free PSA because acridinium ester is capable of provide good sensitivity when detecting low amount of sample, i.e. 0.03 ng/mg of total protein.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Allard et al. (US 6,107,049) further in view of Diamandis (5,688,658).

Allard teaches a two-site immunometric assay method (sandwich method) for determining total PSA or tPSA wherein two anti-PSA antibodies are employed. One of the anti-PSA antibodies is labeled (detection antibody) and the other is immobilized (capture antibody) on a solid phase. The capture and the detection antibodies are contacted simultaneously or sequentially with the test sample. Sequential method can

be accomplished by incubating the capture antibody with the sample and adding the detection antibody; the capture antibody is separated from the liquid test mixture, and the label is measured. Label used in the detection antibody can be selected from any of those known conventionally in the art. Commonly, the label is an enzyme or a chemiluminescent moiety, a fluorophor, a radioisotope. The solid phase to which the capture antibody is immobilized can be magnetic particles, latex particles, etc. (see col. 6, line 64-col. 7, line 45.).

However, Allard fails to teach using acridinium label.

Diamandis teaches using chemiluminescent labels such as acridinium esters in immunoassay to detect prostate specific antigen (PSA). (see col. 5, lines 17-24).

It would have been obvious to one of ordinary skills in the art to use acridinium esters as chemiluminescent label in the immunoassay method of Allard to detect total PSA because acridinium ester is capable of provide good sensitivity when detecting low amount of sample, i.e. 0.03 ng/mg of total protein.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do
Patent Examiner
December 27, 2002

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
01/10/03